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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/063,519	05/01/2002	Audrey Goddard	P3230R1C001-168	8149

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EXAMINER	
BLANCHARD, DAVID J	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 07/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/063,519	GODDARD ET AL.	
	Examiner	Art Unit	
	David J. Blanchard	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/1/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Notice to comply*.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01 May 2006 has been entered.

2. Claim 6 is canceled.

3. Claims 1-5 are pending and under examination.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. This Office Action contains New Grounds of Objection.

Sequence Requirements

6. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). This application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 because this application does not contain as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c). Applicant is required to submit an initial or substitute paper copy of the "Sequence Listing" as well as an amendment directing its entry into the specification and the requisite statement that the paper and computer readable copies are the same and

include no new matter (see attached Notice to Comply). The examiner notes applicants computer readable form of the sequence listing filed 5/3/2002.

7. Any questions regarding compliance with the sequence rules requirements specifically should be directed to the departments listed at the bottom of the Notice to Comply.

8. APPLICANT IS GIVEN THE TIME ALLOTED IN THIS OFFICE ACTION WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 C.R.F. §§ 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. § 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. § 1.136. In no case may an applicant extend the period for response beyond the six-month statutory period. Direct the response to the undersigned.

Response to Arguments

9. The rejection of claims 1-5 under 35 U.S.C 101 because the claimed invention is not supported by a substantial asserted utility or a well-established utility is maintained.

Applicant again summarizes the examiners position, the disputed issues, cites case law and MPEP. Applicant maintains that the asserted patentable utility of the PRO1864 polypeptide is based on the disclosure in Example 18 of the instant application that the mRNA encoding the PRO1864 polypeptide is "more highly expressed" or according to the Grimaldi Declaration, at least two-fold higher in melanoma compared to normal skin tissue.

Applicants argue that Hu is not relevant to the present application, which does not rely on microarray data. In this regard, Applicants rely on Kuo (Exhibit 1, 5/1/2006). Applicants' arguments have been fully considered but they are not persuasive. From the evidence provided it cannot be ascertained if Kuo's microarray data was consistent or inconsistent with Kuo's RT-PCR data. Kuo's poor correlation between microarray and proteomic expression profiles does not speak to changes in mRNA attributable to disease-independent differences between samples. Further, the "good correlation between mRNA and protein expression" was found after treatment with the potent immunostimulating agent CpG. It is not clear what effect, if any, CpG treatment will have on PRO1864 mRNA and polypeptide levels. Further, unlike the present application, Kuo et al actually analyzed mRNA and protein levels and performed functional assays. The instant application merely measures mRNA and presumes that PRO1864 polypeptide levels will track with the changes in PRO1864 mRNA, without providing any evidence of how PRO1864 polypeptide levels change in melanomas compared to normal skin and does not disclose any biological activity or function for the PRO1864 polypeptide. The specification does not provide any evidence that the PRO1864 polypeptide can be used in a diagnostic or therapeutic setting, what information the PRO1864 polypeptide expression provides the clinician, such as the status of the cancer, or the direction in which therapy should proceed.

Applicants argue that the data in Example 18 and the first Grimaldi declaration (Exhibit 1, 5/2/2005) are sufficient to establish the asserted diagnostic utility, and the examiner has not rebutted the presumption of utility afforded Applicants' application.

Applicants argue that the first Grimaldi declaration provides further facts relating to example 18, in that the DNA libraries used in the gene expression studies were made from pooled samples. Applicants argue that the PTO has not supplied any reasons or evidence to question the first Grimaldi declaration. Applicants remind the examiner that Office personnel must accept an opinion from a qualified expert. Applicants' arguments have been fully considered but they are not persuasive.

The first Grimaldi declaration (Exhibit 1, 5/2/2005) has been considered. However, the MPEP makes clear, "factual evidence is preferable to opinion testimony ... ." The MPEP also makes clear, "opinion" testimony is entitled to be considered, i.e., it is "admissible" in an ex parte proceeding. MPEP §716.01(c). The mere fact that opinion testimony is admissible (i.e., is entitled to be considered) does not per se mean it must be accorded controlling weight. In assessing the weight to be given expert testimony in an ex parte context, the examiner may properly consider, among other things:

(1) The nature of the fact sought to be established.

(2) The strength of any opposing evidence.

(3) The interest of the expert in the outcome of the case.

(4) The presence or absence of factual support for the expert's opinion.

Unless an "expert" states the underlying basis for an opinion, it may be difficult to accord the opinion significant weight. Opinions expressed without disclosing the underlying facts or data may be given little, or no, weight.

The assertions that "Data from pooled samples is more likely to be accurate than data obtained from a sample from a single individual" (paragraph 5), "it is reasonable to assume that any detectable differences seen between two samples will represent at least a two fold difference in cDNA" (paragraph 6), "The precise levels of gene expression are irrelevant" (paragraph 7), and "If a difference is detected, ... the gene and its corresponding polypeptide ... are useful for diagnostic purposes" (paragraph 7) are conclusory and unsupported. Although the declaration states that the DNA libraries used in the gene expression studies were made from pooled samples of normal and of tumor tissues, this statement is in contrast to the specification's teachings, which discloses:

> Identification of the differential expression of the PRO polypeptide-encoding nucleic acid in one or more tumor tissues as compared to one or more normal tissues of the same tissue type renders the molecule useful diagnostically for the determination of the presence or absence of tumor in a subject suspected of possessing a tumor as well as therapeutically as a target for the treatment of a tumor in a subject possessing such a tumor. Page 140, paragraph 0530.

It is unknown what level of difference is being reported or how many samples were tested. The declaration does not provide anything specific concerning PRO1864 mRNA expression, PRO1864 polypeptide expression, or the correlation between the two in tumor tissue and normal tissue. Given the paucity of information regarding PRO1864 mRNA expression and the complete lack of data concerning PRO1864 polypeptide expression, Hu is evidence that a skilled artisan would consider the precise level of PRO1864 gene expression as relevant.

The asserted diagnostic utility of the PRO1864 polypeptide depends upon its ability to differentiate normal tissue from tumor tissue. In practicing the invention some

value for PRO1864 polypeptide expression must be obtained in order to make this distinction. Establishing a cutoff value for this distinction would be difficult unless one knows the degree of variation within the pool, which Applicants have not provided. There is no evidence of record concerning the normal range of PRO1864 mRNA levels or PRO1864 polypeptide levels in normal tissue or tumor tissue. There is no evidence of record that a normal range of PRO1864 mRNA or PRO1864 polypeptide levels could be defined that would distinguish normal tissue from tumor tissue. Without a knowledge of the variation within the pool one would not know if any particular measurement from a tissue would indicate normal tissue or tumor tissue. Pooled samples would also obscure the variation between samples, making the disclosed results for PRO1864 polynucleotide expression less useful, accurate and informative than if results from individual samples had been provided. In fact, the range of values from normal and/or tumor tissue could be so broad that it would be impossible to distinguish normal tissue from tumor tissue.

Applicants argue that the PTO argues that because there is no correlation between static mRNA and protein levels one would not know if a change in mRNA is associated with a corresponding change in protein. Applicants' arguments have been fully considered but they are not persuasive. The skilled artisan would not know if or how expression of the PRO1864 polypeptide would change in tumors because there are numerous levels of control of protein synthesis, degradation, processing and modification, which are only apparent by direct protein analysis. See Haynes (Electrophoresis. 1998 Aug;19(11):1862-71; of record):

"it is evident that the analysis of mature protein products in cells is essential as there are numerous levels of control of protein synthesis, degradation, processing and modification, which are only apparent by direct protein analysis" (page 1863, right column, full paragraph 2);

"The multi-level control of protein synthesis and degradation in cells means that only the direct analysis of mature protein products can reveal their correct identities, their relevant state of modification and/or association and their amounts." Page 1870 left column, last full paragraph;

This conclusion is supported by:

Molecular Biology of the Cell, 3rd ed. (Exhibit 4, 5/2/2005):

"other controls can act later in the pathway from DNA to protein to modulate the amount of gene product that is made" (page 453, last full paragraph);

Molecular Biology of the Cell, 4th ed. (Exhibit 5, 5/2/2005):

"the final level of a properly folded protein in a cell therefore depends upon the efficiency with which each of the many steps [from DNA to protein] is performed" (page 363, last full paragraph and page 364, Figure 6-90);

Genes VI (Exhibit 6, 5/2/2005):

"production of RNA cannot inevitably be equated with production of protein" (paragraph bridging pages 847-848).

the declaration of Dr. Polakis under 37 CFR 1.132 (Exhibit 3, 5/2/2005):

"... there have been published reports of genes for which such a correlation does not exist, ..." (paragraph 6);

Meric (Mol Cancer Ther. 2002 Sep;1(11):971-9 (Exhibit 8, 5/2/2005):

Gene expression is quite complicated, however, and is also regulated at the level of mRNA stability, mRNA translation, and protein stability. Page 971, left column, first paragraph of introduction.

See also the Polakis declaration (Exhibit 3, 5/2/2005) wherein it is taught that ~20% of the samples examined do not show a correlation between an increase in the level of mRNA and an increase in the level of the encoded protein (paragraph 5).

With regard to the references of Haynes and Gygi, Applicants argue that these studies only provide teachings regarding the predictability of the correspondence of steady-state mRNA and protein levels, and do not speak to whether or not a detectable change in mRNA level will lead to a detectable change in protein level, and therefore are not relevant to Applicants' argument (pg 9-10). The Examiner finds these arguments persuasive. The Examiner agrees with Applicant that these references do not provide teaching as to whether changes in mRNA expression are generally reflected as changes in protein expression and do not support applicants' argument.

Applicants' analogy with gallons of gas vs. mRNA copies is acknowledged. Applicants' arguments have been fully considered but they are not persuasive. The fact that there may be a commonly understood general rule or dogma that increased mRNA levels are predictive of corresponding increased levels of the encoded protein does not establish the correlation between the change, if any, in PRO1864 transcripts and PRO1864 polypeptide expression in tumors because there are examples of genes for which such a correlation does not exist, as evidenced by the Polakis declaration (Exhibit 3, 5/2/2005).

Applicant submits Exhibit 2 and a second Polakis Declaration (Exhibit 2, 5/1/2006), which identifies 28 gene transcripts out of 31 gene transcripts (i.e., greater than 90%) that showed good correlation between tumor mRNA and tumor protein levels. Applicant refers to the statement in the Polakis Declaration, which says "[a]s such, in the cases we have been able to quantitatively measure both (i) mRNA and (ii) protein levels in both (i) tumor tissue and (ii) normal tissue, we have observed that in the

vast majority of cases, there is a very strong correlation between increases in mRNA expression and increases in the level of protein encoded by that mRNA." This has been fully considered but is not found persuasive. The data presented in Exhibit B merely scores mRNA and protein levels as either "+" or "-" which is insufficient to support applicants' assertion that an increase in mRNA levels corresponds with an increase in the level of the corresponding protein. While the Polakis Declaration refers to being able to quantitatively measure mRNA and protein levels in both tumor tissue and normal tissue, this data is not supplied. Exhibit B does not quantitatively measure both mRNA and protein levels in both tumor tissue and normal tissue and the significance of the symbols "+" and "-" is not clear. Importantly, Exhibit B does not measure the levels of PRO1864 mRNA levels and PRO1864 polypeptide levels in melanomas and normal skin and there are examples of genes for which such a correlation does not exist. Again, the Polakis declaration (Exhibit 3, 5/2/2005) teaches that ~20% of the samples examined do not show a correlation between an increase in the level of mRNA and an increase in the level of the encoded protein (paragraph 5). Further, Lian et al. (2001, Blood 98(3):513-524; IDS reference 74 filed 5/1/06) show a lack of correlation in mammalian (mouse) cells (see p. 514, top of left column: "The results suggest a poor correlation between mRNA expression and protein abundance, indicating that it may be difficult to extrapolate directly from individual mRNA changes to corresponding ones in protein levels."). See also Fessler et al. (2002, J. Biol. Chem. 277(35):31291-31302; IDS reference 7 filed 9/6/05) who found a "[p]oor concordance between mRNA transcript and protein expression changes" in human cells (p. 31291, abstract).

A probable utility does not establish a practical utility, which is established by actual testing or where the utility can be "foretold with certainty." *Bindra v. Kelly*, 206 USPQ 570, 575 (Bd. Pat. Inter. 1979) (Reduction to practice was not established for an intermediate useful in the preparation of a second intermediate with a known utility in the preparation of a pharmaceutical. The record established there was a high degree of probability of a successful preparation because one skilled in the art may have been motivated, in the sense of 35 U.S.C. 103, to prepare the second intermediate from the first intermediate. However, a strong probability of utility is not sufficient to establish practical utility.). Practical utility is a shorthand way of attributing "real-world" value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner, which provides some immediate benefit to the public.

Unlike the situations wherein a claimed compound has been tested and has shown a pharmacological activity and therefore has a therapeutic utility sufficient under the patent laws, or wherein an invention has only limited utility and is only operable in certain applications and therefore has some degree of utility sufficient for patentability, in the present situation Applicants have not provided any testing of the expression of the PRO1864 polypeptide. In the absence of any information on the role, activity or expression of the PRO1864 polypeptide in cancer, the examiner therefore considers the asserted utilities to not be specific and substantial because the skilled artisan would not know if the reported change in PRO1864 transcripts is tumor-dependent or tumor-independent and would not know if or how PRO1864 polypeptide expression would change in cancer. Although the asserted utility may be specific to the claimed invention,

it is not substantial. Therefore, the claimed invention lacks a specific and substantial asserted utility.

Applicants' utility standard would mandate only a showing that it is "not implausible" that the invention will work for its intended purpose. If mere plausibility were the test for how to use a claimed invention, Applicants could obtain patent rights to "inventions" based on a disclosure consisting of little more than guesses as to the likelihood of their success. When one of the guesses later proved true, the "inventor" would be rewarded the spoils instead of the party who demonstrated that the method actually worked. That scenario is not consistent with the statutory requirement that the inventor disclose how to use an invention rather than merely proposing an unproved hypothesis. As set forth in Brenner v. Manson:

> But a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion. "[A] patent system must be related to the world of commerce rather than to the realm of philosophy."

There is a complete absence of data supporting the statements which set forth the desired results of the claimed invention and the countervailing evidence shows that the skilled artisan would not know if the disclosed change in PRO1864 mRNA, is tumor-dependent or tumor-independent and would not know if or how expression of the PRO1864 polypeptide would change in tumors. The examiner maintains that Applicants' have failed to disclose how to use the claimed invention.

Orntoft (Mol Cell Proteomics. 2002 Jan;1(1):37-45; Exhibit 3, 5/1/06) notes that it was only possible to compare mRNA and protein alterations in relatively few cases of well focused abundant proteins (Abstract) and that in the few cases analyzed, mRNA

and protein levels showed a striking correspondence although in some cases we found discrepancies that may be attributed to translational regulation, post-translational processing, protein degradation, or a combination of these (page 44, right column, full paragraph 2) and that it is at present unknown whether DNA copy number is one of the mechanisms behind alteration of these eleven proteins where they found a significant correlation between DNA copy number, mRNA expression, and protein level (page 45, left column, full paragraph 1). Furthermore, Orntoft clearly suggest that both transcript and protein levels need to be analyzed (page 45, left column, full paragraph 2). Unlike Orntoft, Applicants have not provided any testing of PRO1864 polypeptide expression. Plus, there is no evidence of record that either PRO1864 mRNA or PRO1864 polypeptide is abundantly expressed in either tumor tissue or normal tissue. Orntoft does not provide any information regarding PRO1864 mRNA expression, PRO1864 polypeptide expression or the correlation between the two in tumor tissue and normal tissue. Thus, considered as a whole the evidence supports and is consistent with the examiner's position that the skilled artisan would not know if or how PRO1864 polypeptide expression changes in cancer and that the present application fails to disclose to disclose enough information about the invention to make its usefulness immediately apparent to those familiar with the technological field of the invention. In addition, Orntoft used gene expression and profiling techniques (microarrays and proteomics) (page 37. right column, last full paragraph) that Applicants have disparaged as inaccurate.

Exhibits 1-22 (5/1/2006) have been considered. However, none of this evidence discloses anything specific regarding PRO1568 mRNA expression, PRO1568 polypeptide expression, or the correlation between the two in normal tissue and tumor tissue. The exhibits do not provide any data concerning PRO1568 mRNA expression, PRO1568 polypeptide expression, or the correlation between the two in tumor tissue and normal tissue. The fact that there may be a commonly understood general rule or dogma that increased mRNA levels are predictive of corresponding increased levels of the encoded protein does not establish the correlation between the change, if any, in PRO1864 transcripts and PRO1864 polypeptide expression in tumors because there are examples of genes for which such a correlation does not exist, as evidenced by the Polakis declaration (Exhibit 3, 5/2/2005). Regarding Orntoft and Futcher (Exhibit 14, 5/1/2006), there is no evidence of record that PRO1864 mRNA or protein is either abundantly expressed or abundantly under-expressed. Hu et al (1/31/2005) cautions researchers from drawing conclusions based on small changes in transcript expression levels between normal and cancerous tissue.

Applicants are not being asked to prove the asserted diagnostic utility either as a matter of statistical certainty or beyond a reasonable doubt. Rather, the facts to be established are: (i) is the reported change in PRO1864 transcripts tumor-dependent or tumor-independent and, if the reported change is tumor-dependent, is there a corresponding change in PRO1864 polypeptide expression. The specification does not establish if the disclosed change in PRO1864 mRNA expression is one of those cases where this is a correlation between a change in mRNA level and a corresponding

change in the level of the encoded protein. Applicants have not provided any testing of PRO1864 polypeptide expression. Therefore, there is no reason for a skilled artisan to be reasonably convinced that the PRO1864 polypeptide will exhibit the asserted diagnostic behavior. In the absence of any testing of the expression of the PRO1864 polypeptide, the specification does not provide some immediate benefit to the public for the PRO1864 polypeptide and claimed antibodies thereto. The correlation between the disclosed change in PRO1864 mRNA and a change in PRO1864 polypeptide expression is unknown and is not disclosed. Unlike the situations wherein a claimed compound has been tested and has shown a pharmacological activity and therefore has a therapeutic utility sufficient under the patent laws, or wherein an invention has only limited utility and is only operable in certain applications and therefore has some degree of utility sufficient for patentability, in the present situation Applicants have not provided any testing of the expression of the PRO1864 polypeptide.

Applicants should provide substantial evidence of a diagnostic utility unless one of skill in art would accept such utility as obviously correct. There is no indication that a skilled artisan would accept without question that the reported change in PRO1864 transcripts is tumor-dependent or that the PRO1864 polypeptide is differentially expressed in tumor tissue as compared to normal tissue in a manner consistent with the reported change in PRO1864 transcripts. Neither the specification nor any of Applicants' arguments, exhibits, declarations or other evidence provide any specific data disclosing if or how PRO1864 polypeptide expression changes in tumor tissue. Instead, Applicants rely on a general correlation between mRNA expression and

expression of the encoded protein rather than the specific correlation between PRO1864 transcripts and PRO1864 polypeptide expression to argue that it is more likely than not that a change in PRO1864 transcripts is correlated with an assumed change in PRO1864 polypeptide expression. Applicants' arguments, exhibits and declarations only show that it is not implausible that invention will work for its intended purpose. Without any evidence of the expression of PRO1864 in tumor tissue one skilled in the art would be required to do further research to determine whether or not the PRO1864 protein expression correlates with PRO1864 mRNA levels in melanomas compared to normal skin. Such further research requirements make it clear that the asserted utility is not yet in currently available form, i.e., it is not substantial. This further experimentation is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete. M.P.E.P 2107 I states:

> A '"substantial utility" defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

In view of the totality of the evidence, the rejection for lack of utility is proper and is maintained.

10. Claims 1-5 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

New Grounds of Objections

11. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Applicant should restrict the title to the claimed invention, i.e., ANTIBODIES TO PRO1864, or similar title that is clearly indicative of the claimed invention.

Conclusions

12. No claim is allowed.

13. This is a continued examination of applicant's earlier Application. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
David J. Blanchard
571-272-0827

SHEELA HUFF
PRIMARY EXAMINER

Notice to Comply	Application No. 10/063,519	Applicant(s) Goddard et al	
	Examiner David J. Blanchard	Art Unit 1643	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☒ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☐ 7. Other:

Applicant Must Provide:

☐ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the application.**

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216 or (703) 308-2923
For CRF Submission Help, call (703) 308-4212 or 308-2923
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